Complete Summary

GUIDELINE TITLE

Medication-assisted treatment for opioid addiction in opioid treatment programs: Phases of treatment.

BIBLIOGRAPHIC SOURCE(S)

Phases of treatment. In: Batki SL, Kauffman JF, Marion I, Parrino MW, Woody GE, Center for Substance Abuse Treatment (CSAT). Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. p. 101-20. (Treatment improvement protocol (TIP); no. 43).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Opioid addiction

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Psychiatry
Psychology

INTENDED USERS

Nurses
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To provide guidance on patient-centered phases for planning and providing medication-assisted treatment for opioid addiction (MAT) services and evaluating treatment outcomes in an opioid treatment programs (OTPs), including the (1) acute, (2) rehabilitative, (3) supportive-care, (4) medical maintenance, (5) tapering (optional), and (6) continuing-care phases

TARGET POPULATION

Patients with an addiction to opioids who are eligible for medication assisted treatment programs

INTERVENTIONS AND PRACTICES CONSIDERED

Management

Phased Treatment Approach to Medication-Assisted Treatment

1. Acute phase
2. Rehabilitative phase
3. Supportive-care phase
4. Medical maintenance phase
5. Tapering and readjustment phase
6. Continuing-care phase

Strategies and Interventions to Address the following Treatment Issues

1. Alcohol and drug use
2. Mental, medical, and dental problems
3. Chronic diseases (e.g., diabetes, hypertension, seizure disorders, cardiovascular disease)
4. Infectious diseases (e.g., HIV/AIDS, tuberculosis, hepatitis B and C, sexually transmitted diseases)
5. Susceptibility to vaccine-preventable diseases
6. Women's health issues (e.g., pregnancy, family planning services)
7. Co-occurring disorders (psychotic, anxiety, mood, posttraumatic stress, or personality disorders)

8. Vocational and educational needs
9. Basic living issues (e.g., housing, transportation, child care needs)
10. Legal problems
11. Family issues
12. Therapeutic relationship
13. Motivation and readiness for change
14. Acute and chronic pain management
15. Financial problems
16. Employment, formal education, and other income-related issues

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search involved careful consideration of all relevant clinical and health services research findings, practice experience, and implementation requirements.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

After selecting a topic, Center for Substance Abuse Treatment (CSAT) invites staff from pertinent Federal agencies and national organizations to be members of a resource panel that recommends specific areas of focus as well as resources that should be considered in developing the content for the Treatment Improvement Protocols (TIP). These recommendations are communicated to a consensus panel composed of experts on the topic who have been nominated by their peers. This consensus panel participates in a series of discussions. The information and recommendations on which they reach consensus form the foundation of the TIP. The members of each consensus panel represent substance abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A panel chair (or co-chairs) ensures that the contents of the TIP mirror the results of the group's collaboration.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A large and diverse group of experts closely reviews the draft document. Once the changes recommended by these field reviewers have been incorporated, the Treatment Improvement Protocol (TIP) is prepared for publication, in print and on line.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The consensus panel recommends that medication-assisted treatment for opioid addiction (MAT) as provided in opioid treatment programs (OTPs) be conceptualized in terms of phases of treatment so that interventions are matched to levels of patient progress and intended outcomes.

Rationale for a Phased-Treatment Approach and Duration

Variations Within Treatment Phases

The consensus panel emphasizes that treatment phases should not be viewed as fixed steps with specific timeframes and boundaries but regarded as a dynamic continuum that allows patients to progress according to individual capacity. Some patients progress rapidly and some gradually. Some progress through only some phases, and some return to previous phases. Treatment outcomes should be evaluated not only on how many phases have been completed or whether a patient has had to return to an earlier phase but also on the degree to which the patient's needs, goals, and expectations have been met.

Duration of Treatment Within and Across Phases

Decisions concerning treatment duration (time spent in each phase of treatment) should be made jointly by OTP physicians, other members of the treatment team, and patients. Decisions should be based on accumulated data and medical experience, as well as patient participation in treatment, rather than on regulatory or general administrative policy.

Phases of MAT

Acute Phase

Patients Admitted for Detoxification

Although the phases of treatment model is structured for patients admitted for comprehensive maintenance treatment, some patients may be admitted specifically for detoxification from opioids. These patients usually do not wish to be admitted for or do not meet Federal or State criteria for maintenance treatment. Patients admitted for detoxification may be treated for up to 180 days in an OTP. The goals of detoxification are consistent with those of the acute treatment phase as described below, except that detoxification has specific timeframes and MAT endpoints. Detoxification focuses primarily on stabilization with medication (traditionally using methadone but buprenorphine-naloxone tablets are now available), tapering from this medication, and referral for continuing care, usually outside the OTP. During this process, patients' basic living needs and their other substance use, co-occurring, and medical disorders are identified and addressed. Patients also may be educated about the high-risk health concerns and problems associated with continued substance use. They usually are referred to community resources for ongoing medical and mental health care.

Patients admitted for detoxification should have access to maintenance treatment if their tapering from treatment medication is unsuccessful or they change their minds and wish to be admitted for comprehensive MAT. If these patients meet Federal and State admission criteria, their medically supervised withdrawal from treatment medication should end, their medication should be restabilized at a dosage that eliminates withdrawal and craving, and their treatment plans should be revised for long-term treatment.

Patients Admitted for Comprehensive Maintenance Treatment

The acute phase is the initial period, ranging from days to months, during which treatment focuses on eliminating use of illicit opioids and abuse of other psychoactive substances while lessening the intensity of the co-occurring disorders and medical, social, legal, family, and other problems associated with addiction. The consensus panel believes that front-loading highly intensive services during the acute phase, especially for patients with serious co-occurring disorders or social or medical problems, engages patients in treatment and conveys that the OTP is concerned about all the issues connected to patients' addiction. The table below titled "Acute Phase of MAT" summarizes the main treatment considerations, strategies, and indicators of progress during the acute phase.

Acute Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Rehabilitative Phase
Alcohol and drug use	• Schedule weekly drug and alcohol testing • Educate about effects of alcohol and drugs; discourage their consumption • Ensure ongoing patient dialog with staff • Intensify treatment when necessary • Meet with program physician to ensure adequate dosage of treatment medication	• Elimination of opioid-withdrawal symptoms, including craving • Sense of well-being • Ability to avoid situations that might trigger or perpetuate substance use • Acknowledgment of addiction as a problem and motivation to effect lifestyle changes
Medical concerns: • Infectious diseases (e.g., HIV/AIDS, hepatitis, tuberculosis [TB]) • Sickle cell disease • Surgical needs, such as skin or lung abscesses	• Refer patients immediately to medical providers • Vaccinate as appropriate (e.g., for hepatitis A and B)	• Resolution of acute medical crises • Established, ongoing care for chronic medical conditions
Co-occurring disorders: • Psychotic, anxiety, mood, or personality	• Identify acute co-occurring disorders that may need immediate intervention	• Resolution of acute mental crises • Established, ongoing care for chronic disorders

Acute Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Rehabilitative Phase
disorders	• Identify chronic disorders that need ongoing therapy	
Basic living concerns: • Legal and financial concerns • Threats to personal safety • Inadequate housing • Lack of transportation • Childcare needs • Pregnancy • Advocacy	• Assess needs • Refer patient to appropriate services • Work cooperatively with criminal justice system • Explore transportation options • Link to legal advocate, caseworker, or social worker • Identify financial resources • Provide ongoing case management	• Satisfaction of basic food, clothing, shelter, and safety needs • Stabilization of living situation • Stabilization of financial assistance • Resolution of transportation and childcare needs
Therapeutic relationship: • Establishing trust and feeling of support • Addressing myths about MAT	• Advocate adequate dosage • Remain consistent, flexible, and available; minimize waiting times • Provide incentives and emphasize benefits of treatment • Dispel myths about MAT • Educate patient about goals of MAT • Build support system • Build trust	• Regular attendance at counseling sessions • Positive interaction with treatment providers • Focus on treatment goals
Motivation and readiness for change: • Ambivalent attitudes about substance use • Avoidance of	• Ensure adequate dosage • Address ambivalence • Empower patient • Emphasize treatment benefits	• Commitment to treatment process • Ackowledgment of addiction as a problem • Lifestyle changes and addressing addiction-

Acute Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Rehabilitative Phase
counseling (noncompliance) • Negative relationships with staff • Inadequate dosage • Negative attitude about treatment • Involuntary discharge	• Emphasize importance of making a fresh start	related issues

Goals of the Acute Phase

A major goal during the acute phase is to eliminate use of illicit opioids for at least 24 hours, as well as inappropriate use of other psychoactive substances. This process involves:

- Initially prescribing a medication dosage that minimizes sedation and other undesirable side effects
- Assessing the safety and adequacy of each dose after administration
- Rapidly but safely increasing dosage to suppress withdrawal symptoms and cravings and discourage patients from self-medicating with illicit drugs or alcohol or by abusing prescription medications
- Providing or referring patients for services to lessen the intensity of co-occurring disorders and medical, social, legal, family, and other problems associated with opioid addiction
- Helping patients identify high-risk situations for drug and alcohol use and develop alternative strategies for coping with cravings or compulsions to abuse substances.

Indications that patients have reached the goals of the acute phase can include

- Elimination of symptoms of withdrawal, discomfort, or craving for opioids and stabilization
- Expressed feelings of comfort and wellness throughout the day
- Abstinence from illicit opioids and from abuse of opioids normally obtained by prescription, as evidenced by drug tests
- Engagement with treatment staff in assessment of medical, mental health, and psychosocial issues
- Satisfaction of basic needs for food, shelter, and safety

Alcohol, Opioid, and Other Drug Abuse

During the acute phase, OTP staff members should pay attention both to patients' continuing opioid abuse and to their use of other addictive and psychoactive substances. Patients should receive information about how other drugs, nicotine,

and alcohol interact with treatment medications and why medication must be reduced or withheld when intoxication is evident. When substance abuse continues during the acute phase, the treatment team should review patients' presenting problems and revise plans to address them, including changes in dosage, increased drug testing, or other intensified interventions.

In addition, the consensus panel believes that frequent contact with knowledgeable and caring staff members who can motivate patients to become engaged in program activities, especially in the acute phase, facilitates the elimination of opioid abuse.

Co-occurring Disorders

Many people entering OTPs have mental disorders. Persistent, independent co-occurring disorders (i.e., mental disorders that arise from causes other than substance use and need ongoing therapy) and substance-induced co-occurring disorders (i.e., mental disorders directly related to substance use and addiction that probably will improve as the addiction is controlled) should be identified during initial assessment and the acute phase of treatment so that appropriate treatment or referral can be arranged. Patients should be monitored closely for symptoms that interfere with treatment because immediate intervention might prevent patient dropout. Such disorders can be disruptive at the start of MAT, requiring immediate treatment. The course of recovery from substance-induced co-occurring disorders usually follows that of the substance use disorder itself, and these co-occurring disorders typically do not require ongoing treatment after the acute phase. Some patients may require focused, short-term pharmacotherapy, psychotherapy, or both. However, many patients may have co-occurring disorders requiring a thorough psychiatric evaluation and long-term treatment to improve their quality of life.

Medical and Dental Problems

Patients often present with longstanding, neglected medical problems. These problems might require hospitalization or extensive treatment and could incur substantial costs for people often lacking financial resources. In addition, many patients in MAT have neglected their dental health. Once opioid abuse is stopped, these patients often experience pain because the analgesic effects of the opioids have been removed. Such conditions must be recognized, assessed, and treated, either within an OTP or via referral.

Legal Problems

Most correctional systems do not allow MAT. The consensus panel believes that sudden, severe opioid withdrawal caused by precipitous incarceration can endanger health, especially that of patients already experiencing comorbid medical illness, and can increase the risk of suicide in individuals with co-occurring disorders. Therefore, it is critical to address patients' legal problems and any ongoing criminal activity as soon as possible, preferably in the acute phase. On behalf of those on probation or parole or referred by drug courts, program staff members should work cooperatively with criminal justice agencies, educating them about MAT and, with patients' informed consent, reporting patient progress and incorporating continuing addiction treatment into the probation or parole

plan. OTPs should work with local prisons and jails to provide as much support and consultation as possible. When medical care is provided in jails or prisons by contracted health agencies, OTPs should establish contacts directly with these medical providers to improve the care of incarcerated patients in MAT.

Basic Needs

The consensus panel recommends that patients' basic needs such as food, clothing, housing, and safety be determined during the acute phase, if possible, and that referrals be made to appropriate agencies to address these needs.

Patients' living situations should be relatively stable and secure so that treatment can move beyond the acute phase. Before they transition to the rehabilitative phase, patients should begin to develop the coping skills needed to remove themselves from situations of inevitable substance use. A patient's inability to gain this control may necessitate revision of the treatment plan to assist the patient in moving past the acute phase. The process often includes meeting directly with the patient to assess motivation and adequacy of dosage and to define treatment goals clearly.

Therapeutic Relationships

Positive reinforcement of a patient's treatment engagement and compliance, especially in the acute phase, is important to elicit a commitment to therapy.

Furthermore, participation in peer support services and mutual-help groups (provided that these groups support MAT) can be helpful to patients. OTPs can provide information about appropriate meetings and peer support.

The consensus panel recommends that patients be introduced to key OTP staff members as early as possible during the acute phase to foster an atmosphere of safety, trust, and familiarity. Patients consistently report that a strong therapeutic relationship is one of the most critical factors influencing treatment outcomes and that therapists' warmth, positive regard, and acceptance are major elements in relationship development. Treatment providers should minimize waiting times during scheduled appointments to demonstrate that they value patients' time. In addition, when providers remain flexible and available during the acute phase, they contribute to patients' sense of security. Knowing how to reach staff in an emergency can foster patients' trust in treatment providers.

Motivation and Patient Readiness

Patient motivation to engage in treatment is a predictor of retention and should be reassessed continually. Counselors should explore and address patients' negative treatment experiences. It might help to acknowledge the weaknesses of past staff efforts and to focus on future actions to move treatment forward.

The level of patient engagement during the acute phase is critical. Research has shown that patient motivation, staff engagement, and the trust developed during orientation and the acute phase are linked more closely to treatment outcomes than patients' initial reasons for entering an OTP.

Transition to the Rehabilitative Phase

The panel recommends the following criteria for transition from the acute to the rehabilitative phase:

- Amelioration of signs of opioid withdrawal
- Reduction in physical drug craving
- Elimination of illicit-opioid use and reduction in other substance use, including abuse of prescription drugs and alcohol
- Completion of medical and mental health assessment
- Development of a treatment plan to address psychosocial issues such as education, vocational goals, and involvement with criminal justice and child welfare or other social service agencies as needed
- Satisfaction of basic needs for food, clothing, shelter, and safety

Rehabilitative Phase

The primary goal of the rehabilitative phase of treatment is to empower patients to cope with their major life problems--drug or alcohol abuse, medical problems, co-occurring disorders, vocational and educational needs, family problems, and legal issues--so that they can pursue longer term goals such as education, employment, and family reconciliation. Stabilization of dosage for opioid treatment medication should be complete, although adjustments might be needed later, and patients should be comfortable at the established dosage for at least 24 hours before the rehabilitative phase can proceed. The table below titled "Rehabilitative Phase of MAT" summarizes the treatment issues addressed during the rehabilitative phase, strategies for addressing them, and indicators for subsequent transition to the supportive-care phase.

Rehabilitative Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
Alcohol and drug use • Continued opioid use • Continued abuse of other substances (e.g., alcohol, cocaine, nicotine)	• Begin behavioral contracting • Start short-term inpatient treatment • Introduce disulfiram for alcohol abuse • Provide pharmacotherapy and cessation groups for tobacco use • Intensify	• Ability to identify and manage relapse triggers • Repertoire of coping skills • Demonstrated changes in life circumstances to prevent relapse • Discontinuation of opioid and other drug use • Absence of problem alcohol use • Smoking

Rehabilitative Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
	treatment services • Introduce positive incentives: take-home medication, recognition of progress • Adjust dosage as necessary to prevent continued opioid use • Encourage participation in support groups and family therapy	cessation plan
Medical concerns • Chronic diseases (e.g., diabetes, hypertension, seizure disorders, cardiovascular disease) • Infectious diseases (e.g., HIV/AIDS, TB, hepatitis B and C, sexually transmitted diseases) • Susceptibility to vaccine-preventable diseases • Dental problems, nicotine dependence • Women's health issues (e.g., pregnancy, family planning services)	• Ensure onsite primary care or link to other services • Provide integrated treatment approach • Provide routine TB testing as appropriate • Provide education on diet, exercise, smoking cessation • Provide vaccinations as indicated • Adjust	• Compliance with treatment for chronic diseases • Improved overall health status • Improved dental health and hygiene • Regular prenatal care • Stable medical and mental health status

Rehabilitative Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
	other medications that interfere with treatment medication or adjust dosage of treatment medication • Assess need and refer patient for pain management	
Co-occurring disorders • Psychotic, anxiety, mood, posttraumatic stress, or personality disorders	• Evaluate status • Teach coping skills • Ensure early identification and referral for co-occurring disorders • Refer for psychotropic medication or psychotherapy as indicated	• Stable mental status and compliance with psychiatric care
Vocational and educational needs • Unemployment/underemployment • Low reading skills • Illiteracy	• Identify education deficiencies • Provide onsite general equivalency	• Stable source of income • Active employment search • Involvement in productive

Rehabilitative Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
• Learning disabilities	diploma (GED) counseling or referral • Provide literacy and vocational training with community involvement • Provide training on budgeting of personal finances • Provide employment opportunities or referral to a job developer	activity: school, employment, volunteer work
Family issues • Absence of family support system • Emergence of family problems (e.g., traumatic family history, divorce, other problem situations)	• Involve community or faith-based, fellowship, recreation, or other peer group • Increase involvement in family life (in absence of family dysfunction that impedes progress) • Provide for well-child care	• Social support system in place • Absence of major conflict within support system • Increased responsibility for dependents

Rehabilitative Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
Legal problems: • Criminal charges • Custody battles • Ongoing illegal activities	• Provide access to legal counsel • Encourage patient to take responsibility for legal problems • Identify obstacles to eliminating illegal activities and replace them with constructive activities	• Resolution of, or ongoing efforts to solve, legal problems • Absence of illegal activities

As stated for the acute phase, during the rehabilitation phase treatment, providers should continue to assist or provide referrals for patients who need help with legal, educational, employment, medical, and financial problems that threaten treatment retention.

Throughout this phase, efforts should increase to promote participation in constructive activities such as full- or part-time employment, education, vocational training, child rearing, homemaking, and volunteer work. As patients attend to other life domains, requirements for frequent OTP attendance or group participation should not become barriers to employment, education, or other constructive activities or medical regimens. Consequently, program policies in areas such as take-home medications and dosing hours should be more flexible in the rehabilitative phase, especially when patients must travel long distances to their OTP or receive medication at restricted hours.

The consensus panel recommends that information about outside support groups, including faith-based, community, and 12-Step groups, be reviewed with patients in the rehabilitative phase and that patients be urged to participate in such groups, assuming that these groups support MAT. OTPs also should cultivate direct relationships with organizations that might lend support for patient recovery. Faith-based organizations can provide spiritual assistance, a sense of belonging, and emotional support, as well as opportunities for patients to contribute to their communities, and in the process can educate community members about MAT.

Relapse triggers or cues such as boredom, certain locations, specific individuals, family problems, pain, or symptoms of co-occurring disorders might recur during the rehabilitative phase and trigger the use of illicit drugs or abuse of prescription drugs or alcohol. Helping patients develop skills to cope with triggers should be emphasized in this phase and might involve individual, group, or family counseling or participation in groups focused on relapse prevention.

Many factors that receive emphasis in the acute phase should continue to be addressed in the rehabilitative phase:

- Continued alcohol and prescription drug abuse and use of illicit drugs
- Ongoing health concerns
- Acute and chronic pain management
- Employment, formal education, and other income-related areas
- Family relationships and other social supports
- Legal problems
- Co-occurring disorders
- Financial problems

Continued Alcohol and Prescription Drug Abuse and Use of Illicit Drugs

The consensus panel recommends that elimination of alcohol abuse, illicit-drug use, and inappropriate use of other substances be required to complete the rehabilitative phase. Evidence of heavy alcohol use might warrant that a patient return to the acute phase. If a patient is using medications, particularly drugs of potential abuse prescribed by a nonprogram physician, the patient should be counseled to advise his or her OTP physician of these prescriptions and should sign an informed consent statement permitting OTP staff and the outside physician to discuss these prescriptions. If drug use is illicit or unapproved by the OTP physician, then group, family, and individual counseling should continue, and the patient should remain in the rehabilitative phase. Patients who continue to use illicit drugs or demonstrate alcohol use problems are not eligible for take-home medication. Take-home medication should not be considered until these patients have demonstrated a period of abstinence. Patients also should receive information on the risks of smoking, both for their own recovery and for the health of those around them.

The frequency of drug testing during the rehabilitative phase and all subsequent phases should depend on a patient's progress in treatment. The consensus panel recommends that, once a patient is progressing well and has consistently negative drug tests, the frequency of random testing be decreased to once or twice per month. The criteria for this should be part of the treatment plan.

Ongoing Health Concerns

As patients advance in the rehabilitative phase, they should attend to other medical problems, and OTP staff should help them navigate the medical- and dental-care systems, while educating practitioners about MAT. Onsite primary health care is optimal and has been instituted successfully in many OTPs and can result in better outcomes for patients, although it requires careful coordination of activities and staff. When lack of resources precludes onsite medical services in an OTP, referral arrangements with other service providers should be in place.

The consensus panel recommends a more integrated approach to patient health in the rehabilitative phase. A patient's health needs should be diagnosed and treated immediately. Education about topics with longer term benefits, such as nutrition, exercise, personal hygiene, sleep, and smoking cessation, can be started. Eventually, patients should demonstrate adherence to medical regimens for their chronic conditions and address any acute conditions before they are considered for transition from the rehabilitative phase to subsequent treatment phases.

Acute and Chronic Pain Management

Because acute pain treatment usually involves opioid medications, programs should work with patients to recognize the risk of relapse and provide supports to prevent it.

Employment, Formal Education, and Other Income-Related Issues

The consensus panel believes that some of the most difficult obstacles to a stable life for MAT patients include unemployment and inadequate funds to live comfortably and safely. Most such limitations should be addressed during the rehabilitative phase.

Individuals who need access to high-quality social services should be identified during the rehabilitative phase for educational, literacy, and vocational programs that will equip them with the skills needed to function independently.

Ideally, OTPs should provide onsite general equivalency diploma (GED) counseling and assistance or make referrals to local adult education programs that are sensitive to the needs of patients in MAT. Efforts can be made to encourage business, industry, and government leaders to create income-generating enterprises that provide patients with job skills and opportunities for entry into the job market and to preclude employment discrimination for patients.

Patients in MAT face unique employment challenges, especially as employers increasingly impose preemployment drug testing and patients must wrestle with whether to disclose their status. The panel recommends that vocational training provided in an OTP include basic education about drug testing, including the fact that methadone may be detected. Patients should be advised to answer all job application questions honestly and should be counseled on ways to manage disclosure of their treatment status. Patients with disabilities should be educated about the basics of the Americans with Disabilities Act and any local antidiscrimination legislation and enforcement.

By the end of the rehabilitative phase, patients should be employed, actively seeking employment, or involved in a productive activity such as school, child rearing, or regular volunteer work. They should have a stable source of legal income, whether from employment, disability benefits, or other legitimate sources, ensuring that they can avoid drug dealing or other criminal activities to obtain money.

Family Relationships and Other Social Supports

Broken trust, disappointment, anger, and conflict with family members and acquaintances are realities that patients should face during the rehabilitative phase. Many need to reconcile with their families, reunite with or regain custody of their children, and handle other family issues. Some patients have had little or no family contact during the period of their opioid addiction. Counselors need to help patients improve their social supports and relationships and begin to rebuild and heal severely damaged family relationships.

Transition from the rehabilitative phase should require that patients have a social support system in place that is free of major conflicts and that they assume increased responsibility for their dependents (e.g., by reliably providing child support).

Legal Problems

The stress associated with patients' legal problems can precipitate relapse to illicit drug use or abuse of alcohol or prescription drugs. Counselors should probe patients' legal circumstances, such as child custody obligations, and patients should be encouraged to take responsibility for their actions; however, counselors should help patients remain in treatment while resolving pending legal problems. During the rehabilitative phase, counselors should help patients overcome guilt, fear, or uncertainty stemming from their legal problems. In addition, OTP staff should ensure that patients have access to adequate legal counsel, for instance, through a public defender. All major legal problems should be in the process of resolution before patients move beyond the rehabilitative phase. Drug courts' referrals of patients can result in reporting requirements and specialized protocols.

Co-occurring Disorders

The consensus panel recommends that, before patients move beyond the rehabilitative phase, co-occurring disorders be alleviated or stabilized. Although symptoms might continue to arise, patients should have adequate coping skills to avoid relapse to opioid abuse.

Supportive-Care Phase

After meeting the criteria for transition from the rehabilitative phase, patients should progress to the supportive-care phase, in which they continue opioid pharmacotherapy, participate in counseling, receive medical care, and resume primary responsibility for their lives. During this phase, patients should begin to receive take-home medication for longer periods and be permitted to make fewer OTP visits. Depending on regulations (State regulations often are more stringent than Federal), these patients might visit their OTP as infrequently as every other week. Often, supportive care provided in an OTP can be augmented by supportive activities through mutual-help, community, faith-based, peer, and acculturation groups.

The table below titled "Supportive-Care Phase of MAT" summarizes the treatment issues that should be addressed during the supportive-care phase, strategies for addressing them, and indicators for the subsequent transition from the supportive-care phase to medical maintenance or tapering.

Supportive-Care Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to Next Phase
Alcohol and drug use	• Monitor use • Increase frequency of drug screening	• Discontinued drug use and no problems with alcohol use
Medical and mental health concerns	• Monitor compliance with medical/psychiatric regimens • Maintain communication with patients' health care and mental health care providers	• Stability
Vocational and educational needs	• Monitor vocational status and progress toward educational goals • Assist in addressing workplace problems	• Stable source of income
Family issues	• Monitor family stability and relationships • Refer for family therapy as needed	• Stability
Legal issues	• Monitor ongoing legal issues • Provide needed support	• Resolution

Patients should have discontinued alcohol and prescription drug abuse and all illicit-drug use, as well as any involvement in criminal activities, before entering the supportive-care phase. Heavy or problem substance use should result in patients' return to the acute phase. Patients in supportive care should be employed, actively seeking employment, or involved in other productive activities, and they should have legal, stable incomes. Even though all treatment plans and patients' progress should be assessed individually, if any requirements largely are unmet, counselors should consider returning these patients to the rehabilitative phase to address areas of renewed concern rather than advancing them to the medical maintenance or tapering phase.

After patients in supportive care are abstinent from illicit drugs or are no longer abusing prescription drugs (as confirmed by treatment observation and negative drug tests) for a specified period, they should be considered for transition to either the medical maintenance or the tapering phase. Opinions vary on the length of time patients should be free from illicit-drug use and abuse of prescription drugs before being allowed to move to the next phase. However, to receive the maximum 30-day supply of take-home medication, a patient must be demonstrably free from illicit substances for at least 2 years of continuous treatment. The consensus panel believes that a period of treatment compliance lasting between 2 and 3 years usually is appropriate. However, the length of time a patient remains in supportive care should be based entirely on his or her needs and progress, not on an imposed timetable. Patients' progress in coping with their

life domains should be assessed at least quarterly to determine whether patients are eligible and ready for transition from supportive care to either the medical maintenance or tapering phase.

In some cases, patients who stop opioid abuse and demonstrate compliance with program rules do not make progress in other life domains. Although such patients might do well in MAT, they still need the ongoing support and pharmacotherapy provided by the OTP and, in the opinion of the consensus panel, should be deemed ineligible or inappropriate candidates for either medical maintenance or tapering. Instead, these patients should continue to receive take-home medication for brief periods (e.g., 1 to several days) along with other services as needed.

The criteria for transitioning to the next phase of treatment depend on whether the patient is entering the medical maintenance phase or the tapering and readjustment phase.

Medical Maintenance Phase

In the medical maintenance phase, stabilized patients who continue to require medication to remain stable are allowed longer term (up to 30-day) supplies of take-home medication and further reductions in the frequency of treatment visits, generally without the suite of services included in comprehensive MAT. Medical maintenance with methadone can be administered through an OTP or through the office of a qualified physician who operates under Substance Abuse and Mental Health Services Administration (SAMHSA) approval as a "medication unit" and is linked formally to an OTP. Federal regulations permit various levels of take-home medication for unsupervised use, with the amount linked to the length of time that patients have been abstinent from illicit opioids or have stopped abusing prescription opioids and to other specified conditions. Some State regulations (e.g., New York) further restrict the amount of take-home opioid treatment medication and supersede Federal regulations.

The consensus panel recommends the following criteria to determine a patient's eligibility for the medical maintenance phase of treatment:

- 2 years of continuous treatment
- Abstinence from illicit drugs and from abuse of prescription drugs for the period indicated by Federal and State regulations (at least 2 years for a full 30-day maintenance dosage)
- No alcohol use problem
- Stable living conditions in an environment free of substance use
- Stable and legal source of income
- Involvement in productive activities (e.g., employment, school, volunteer work)
- No criminal or legal involvement for at least 3 years and no current parole or probation status
- Adequate social support system and absence of significant unstabilized co-occurring disorders

During the medical maintenance phase, OTPs may play various roles in patients' primary medical and mental health care. OTPs that provide only limited health care services should integrate their services with those of other health care

providers. The table below entitled "Medical Maintenance Phase of MAT" summarizes treatment issues and strategies in the medical maintenance phase of MAT and provides indicators for transition to physician's office-based opioid treatment (OBOT) or the tapering or continuing-care phases.

Medical Maintenance Phase of MAT		
Treatment Issue	Strategies To Address Issue	Indications for Transition to OBOT or Tapering or Continuing-Care Phases
Alcohol and drug use	• Monitor use • Perform drug testing	• Continuous stability for 2 years
Medical and mental health concerns	• Monitor compliance • Maintain communication	• Stability
Vocational and educational needs	• Monitor progress • Remain available to address workplace problems	• Stability
Family issues	• Monitor family stability • Refer to family therapy as needed	• Stability
Legal issues	• Monitor ongoing legal issues • Provide support as needed	• Stability

In addition, evaluation of life domains including substance use, co-occurring medical and mental problems, vocational and educational needs, family circumstances, and legal issues should continue during the medical maintenance phase, regardless of the setting. Although patients in medical maintenance may not require psychological services, they may need occasional dosage adjustments based on their use of other prescription medication or on such factors as a change in metabolism of methadone.

The consensus panel recommends random drug testing and callbacks of medication during the medical maintenance phase to make sure that patients are adhering to their medication schedules. Patients in medical maintenance should be monitored for risk of relapse. Positive drug test results should be addressed without delay, and patients should be returned to the rehabilitative phase when appropriate.

The consensus panel recommends that, as part of the diversion control plan required for all OTPs by SAMHSA, evidence of medication diversion by a patient in medical maintenance result in reclassification of that patient to the most

appropriate previous phase of treatment and in adjustment of treatment, other services, and privileges. Reinstatement into medical maintenance should occur only after the phase-regressed patient is observed over a reasonable period (at least 3 to 6 months) and has demonstrated required progress.

Considerations for OBOT with Methadone

OBOT may be considered for patients receiving methadone in MAT in an OTP who have demonstrated stability in all domains for at least 2 consecutive years of treatment. If a patient in medical maintenance who is receiving treatment through OBOT relapses (to opioid, other drug, or alcohol abuse) or needs the structure of an OTP for psychosocial reasons, the treating physician is responsible for referring the patient back to an OTP. There are some exceptions in which patients, early in treatment, can be transferred from an OTP to OBOT with methadone (e.g., when travel to an OTP is impossible or there are medical reasons), but these exceptions must be preapproved by SAMHSA.

Coordination of care is critical in the OBOT model so that patients get the full range of services needed to remain abstinent. Treatment issues listed in the tables above also are applicable to patients who receive OBOT. Regardless of the opioid treatment medication used, treatment of opioid addiction requires a comprehensive and individualized treatment approach that includes medication and counseling services. Even for patients who are rehabilitated and stable enough to qualify for medical maintenance, medication alone often is inadequate to treat their opioid addiction.

Tapering and Readjustment Phase

It is important that any decision to taper from opioid treatment medication be made without coercion and include careful consideration of a patient's wishes and preferences, level of motivation, length of addiction, results of previous attempts at tapering, family involvement and stability, and disengagement from activities with others who use substances. A patient considering dose tapering should understand that the chance of relapse to drug use remains and some level of discomfort exists even if the dose is reduced slowly over months. Patients should be assured that they temporarily can halt the reductions or return to a previous methadone dosage if tapering causes problems.

As medication is being tapered, intensified services should be provided, including counseling and monitoring of patients' behavioral and emotional conditions. Patients considered for medication tapering should demonstrate sufficient motivation to undertake this process, including acceptance of the need for increased counseling. Tapering from medication can be difficult, and patients should understand the advantages and disadvantages of both tapering from and continuing on medication maintenance as they decide which path is best for them. The table below titled "Tapering Phase of MAT" presents treatment issues during the tapering phase, strategies to address these issues, and indicators for return to a previous phase.

Tapering Phase of MAT

Treatment Issue	Strategies To Address Issue	Indications for Return to a Previous Treatment Phase
Alcohol and drug use	• Monitor use • Increase drug testing • Increase counseling support	• Relapse or concern about relapse to opioid use • Positive drug test for an illicit substance
Medical and mental health concerns	• Monitor compliance • Maintain communication with health care providers • Continue education	• Unstable health issues
Vocational and educational needs	• Monitor progress • Be available to address workplace problems	• Instability • Loss of employment
Family issues	• Monitor family stability • Refer to family therapy as needed	• Instability • Death or loss of loved one • Unstable housing
Legal issues	• Monitor ongoing legal issues • Provide support as needed	• New criminal involvement

Reasons for Tapering

Sometimes decisions to taper are motivated by the hardships of OTP attendance and other requirements or by the stigma often associated with MAT. The consensus panel urges OTPs to identify such situational motives and ensure that patients who choose medically supervised withdrawal from MAT are motivated instead by legitimate concerns about health and relapse.

Patients and treatment providers might fail to realize or understand that continuing or long-term MAT is the best choice for some patients. OTP staff members consciously or inadvertently might convey that tapering is more desirable or expected than continuing opioid pharmacotherapy, through such practices as celebrating patients' tapering but not the accomplishments of others who successfully continue in MAT. The consensus panel believes that a basic grounding in MAT pharmacology, the biology of addiction, and the endorphin system helps patients and treatment providers understand that both successful tapering from and continued compliance with medical maintenance treatment are legitimate goals and commendable accomplishments.

Relapse after Tapering

The risk of relapse during and after tapering is significant because of the physical and emotional stress of attempting to discontinue medication. The consensus panel recommends that patients be encouraged to discuss any difficulties they experience with tapering and readjustment so that appropriate action can be taken to avoid relapse. Patients should be persuaded to return to a previous phase if the need is indicated at any time during tapering. Patients also should be told that they can taper at their own rate, that successful tapering sometimes takes many months, and that they can stop tapering or increase their dosage at any time without a sense of failure. Patients should be educated about how to reenter MAT if they believe that relapse is imminent.

Readjustment

Many patients who complete tapering from opioid medication continue to need support and assistance, especially during the first 3 to 12 months, to readjust to a lifestyle that is free of both maintenance medication and substances of abuse. During this period, treatment providers should focus on reinforcing patients' coping and relapse prevention skills. Patients' primary goals should be to increase self-sufficiency and maintain balanced, stable, and productive lifestyles. Participation in 12-Step or other mutual-help groups is recommended as reliance on the OTP is gradually reduced. Motivated patients might be helped by continued naltrexone therapy, which blocks opioid effects for 2 to 3 days in appropriate doses. Care must be taken to initiate naltrexone well after tapering is completed to avoid precipitating withdrawal symptoms. Other patients might benefit from continued counseling to strengthen relapse prevention skills. Some patients might find the support of continued drug testing helpful after tapering. Other recommended strategies include problem solving counseling approaches, reinforcement of positive behaviors and attitudes, an open-door policy to maximize availability of counselors and providers, steps to strengthen patients' own support systems, and development of a relapse prevention plan, including how to return to MAT if necessary.

Reversion to MAT

The consensus panel recommends that all patients attempting tapering be counseled that a return to medication and a previous phase does not represent failure but simply that medical maintenance is more appropriate for some patients in general and for others at particular times in their lives.

Indicators for Transition

Successful discontinuation of medication is a key indicator for transition from the tapering phase to the continuing-care phase. Another key indicator is a positive self-image as someone who feels and functions well without medication. Adoption of a socially productive lifestyle without involvement with substances of abuse also is critical to completing this phase and to continued recovery. The absence of signs and symptoms of abuse or dependence, as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision, (DSM-IV-TR) indicates successful completion of tapering.

Continuing-Care Phase

Continuing care is the phase that follows successful tapering and readjustment. Treatment at this stage comprises ongoing medical follow-up by a primary care physician, occasional check-ins with an OTP counselor, and participation in recovery groups. Ongoing treatment, although less intense, often is necessary because the chronic nature of opioid addiction can mean continuous potential for relapse to opioid abuse for some patients.

Patients in continuing care should have a socially productive lifestyle, no involvement with drugs or problem involvement with alcohol, and improved coping skills demonstrated over at least 1 year. Significant co-occurring disorders should be well under control. People in this phase should continue to participate regularly in mutual-help groups, but regular attendance at an OTP should be unnecessary, except to return to a more intensive level of treatment if necessary for continuation of recovery.

The panel recommends that appointments with the OTP continue to be scheduled every 1 to 3 months, although many programs prefer that patients in continuing care maintain at least monthly contact. Although many programs curtail this contact after 6 to 12 months, others maintain ongoing contact with patients to assist them in maintaining their medication-free lifestyle. Some patients might not need continuing-care services after tapering, preferring instead a complete break from the OTP. Others might need more extensive continuing care, perhaps including referral to a non-MAT outpatient program that more closely fits their needs.

Transition Between Treatment Phases in MAT

Characteristics of the recommended treatment phases are not immutable, and the criteria for transition between phases are not intended to be rigidly interpreted or enforced. The treatment system should be flexible enough to allow for transition according to a patient's progress and circumstances. The program should modify treatment based on the best interests of patients, rather than infractions of program rules.

Occasional relapses to drug use might not require that a patient return to the acute phase but instead that he or she receive intensified counseling, lose take-home privileges, or receive a dosage adjustment. If a patient is in the medical maintenance phase or the tapering and readjustment phase, a relapse often requires a rapid response and change of phase. In these cases, the patient might be reclassified into the rehabilitative phase. After providing evidence that problems are under control, the patient might be able to return to the supportive-care or medical maintenance phase.

Readmission to the OTP

The consensus panel emphasizes that patients almost always should be encouraged to remain in treatment at some level and that pharmacotherapy should be reinstituted unreservedly for most previously discharged patients if and when relapse occurs or seems likely. Feelings of shame, disappointment, and relapse-related guilt, especially for rehabilitated patients who have close relationships with staff members, should not be allowed to inhibit patients from seeking reentry to treatment. The consensus panel recommends that all patients

be informed at entry to the OTP that subsequent reentry is common and can be accomplished more quickly than initial intake because regulations waive documentation of past addiction for returning patients. All obstacles to reentry should be minimized.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on a combination of clinical experience and research-based evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of patient centered phases for planning and providing medication-assisted treatment for opioid addiction (MAT) services and evaluating treatment outcomes to enable optimal treatment outcomes

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The opinions expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), or Department of Health and Human Services (DHHS). No official support of or endorsement by CSAT, SAMHSA, or DHHS for these opinions or for particular instruments, software, or resources described in this document is intended or should be inferred. The guidelines in this document should not be considered substitutes for individualized client care and treatment decisions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Chapter 14, Administrative Considerations, in the original guideline document, covers the challenging administrative aspects of managing and staffing the complex and dynamic environment of an opioid treatment program (OTP). Successful treatment outcomes depend on the competence, values, and attitudes

of staff members. To develop and retain a stable team of treatment personnel, program administrators must recruit and hire qualified, capable, culturally sensitive individuals; offer competitive salaries and benefit packages; and provide good supervision and ongoing training. Implementing community relations and community education efforts is important for opioid treatment programs. Outreach and educational efforts can dispel misconceptions about medication-assisted treatment for opioid addiction and people in recovery. Finally, the chapter provides a framework for gathering and analyzing program performance data. Program evaluation contributes to improved treatment services by enabling administrators to base changes in services on evidence of what works. Evaluation also serves as a way to educate and influence policymakers and public and private payers.

Refer to Chapter 14 in the original guideline document for full details (see "Companion Documents" field in this summary).

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Phases of treatment. In: Batki SL, Kauffman JF, Marion I, Parrino MW, Woody GE, Center for Substance Abuse Treatment (CSAT). Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. p. 101-20. (Treatment improvement protocol (TIP); no. 43).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE COMMITTEE

Treatment Improvement Protocol (TIP) Series 43 Consensus Panel

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Library of Medicine Health Services/Technology Assessment (HSTAT) Web site. Also available in Portable Document Format (PDF) from SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) Web site.

Print copies: Available from the National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20852. Publications may be ordered from NCADI's Web site or by calling (800) 729-6686 (United States only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Executive summary. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. xvii-xx. (Treatment improvement protocol (TIP); no. 43).
- Introduction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 1-10. (Treatment improvement protocol (TIP); no. 43).
- History of medication-assisted treatment for opioid addiction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 11-23. (Treatment improvement protocol (TIP); no. 43).
- Pharmacology of medications used to treat opioid addiction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 25-42. (Treatment improvement protocol (TIP); no. 43).
- Administrative considerations. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 225-240. (Treatment improvement protocol (TIP); no. 43).

- Appendix D: Ethical considerations in MAT. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 297-304. (Treatment improvement protocol (TIP); no. 43).

Electronic copies: Available from the National Library of Medicine Health Services/Technology Assessment (HSTAT) Web site. Also available in Portable Document Format (PDF) from SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) Web site.

The following are also available:

- Knowledge Application Program. KAP keys for clinicians. Based on TIP 43: Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. 20 p. Electronic copies: Available in Portable Document Format (PDF) from the SAMHSA Web site.
- Quick guide for clinicians. Based on TIP 43: Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. 39 p. Electronic copies: Available in Portable Document Format (PDF) from the SAMHSA Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 22, 2005. The information was verified by the guideline developer on January 23, 2006.

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